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Moving forward to achieve universal health coverage in Indonesia

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DOI:
10.33612/diss.124431881

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Document Version
Publisher's PDF, also known as Version of record

Publication date:
2020

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):
Wasir, R. (2020). *Moving forward to achieve universal health coverage in Indonesia*. [Thesis fully internal (DIV), University of Groningen]. University of Groningen. https://doi.org/10.33612/diss.124431881

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Chapter 3

The implementation of health technology assessment (HTA) in medicine pricing and reimbursement policies in Indonesia: insights from multiple stakeholders

The implementation of HTA in Indonesia

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This chapter is based on the published manuscript:
Wasir R, Irawati S, Makady A, Postma M, Goettsch W, Feenstra T, et al. (2019) The implementation of HTA in medicine pricing and reimbursement policies in Indonesia: Insights from multiple stakeholders. PLoS ONE 14(11): e0225626. https://doi.org/10.1371/journal.pone.0225626

Abstract

Objectives

This study aimed to identify the barriers and facilitators to improve the use of health technology assessment (HTA) for the selection of medicines listed in the e-Catalogue and the national formulary in Indonesia.

Methods

Semi-structured interviews were conducted to collect qualitative data. Purposive sampling was used to recruit the stakeholders consisting of policymakers, a pharmaceutical industry representative, healthcare providers, and patients. The data were analyzed using directed content analysis and following the COnsolidated criteria for REporting Qualitative studies (COREQ).

Results

The twenty-five participants interviewed agreed with the use of HTA for supporting the e-Catalogue and the national formulary and perceived the advantages of HTA implementation outweighed the disadvantages. Barriers mentioned were a lack of capability of local human resources, financial incentives, a clear framework and insufficient data. Strategies suggested to overcome the barriers were establishing (inter)national networks to build up capacity, setting up departments of HTA in several universities in Indonesia, and introducing a clear HTA framework. Facilitators mentioned were the ambition to achieve universal health coverage, the presence of legal frameworks to implement HTA in the e-Catalogue and the national formulary, and the demands for appropriate medicine policies.

Conclusions

Several barriers are currently hampering broad implementation of HTA in medicine pricing and reimbursement policy in Indonesia. Solutions to these issues appear feasible and important facilitators exist.

Introduction

The 2015 transition from Millennium Development Goals to Sustainable Development Goals has triggered a shift in global health from service-specific targets to broader health system goals[1]. Target 3.8 of the Sustainable Development Goals explicitly states to achieve Universal Health Coverage (UHC)[2]. UHC will be accomplished when all people receive the healthcare services they need of sufficient quality and without suffering financial hardship. Therefore, the presence of UHC ideally will reduce or eliminate the proportion of out-of-pocket payments from healthcare expenditures[3]. Out-of-pocket payment, a direct payment to the healthcare providers at the time of service use, can drive an individual or a household below the poverty line[4]. In low middle-income countries (LMICs), the proportion of out-of-pocket payments in healthcare expenditures is still high, particularly for medicines, the number ranges from 50% to 90 %[5].

Appropriate medicine policies combined with an implementation of health technology assessment (HTA) can facilitate countries to reduce the out-of-pocket payments for medicines on their way towards UHC. For instance, the United Kingdom (UK) and Thailand, as one of the oldest and the newest UHC examples respectively, have shown that the implementation of HTA supports their medicine policies[6]. Furthermore, the World Health Organization (WHO) highly recommends the use of HTA to facilitate the creation of a list of medicines in the medicine benefit package[7]. The WHO defines HTA as the systematic evaluation of properties, effects and/or impacts of health technologies and interventions[8]. HTA is a critical component of evidence-based policy decision making[7,9].

In response to target 3.8 of the Sustainable Development Goals, the Government of Indonesia launched a new national health insurance system, which is called *Jaminan Kesehatan Nasional – Kartu Indonesia Sehat* (JKN-KIS) in 2014. The JKN-KIS aims to achieve UHC by 2020 and is managed by Indonesia's National Healthcare Security Agency, namely *Badan Penyelenggara Jaminan Sosial Kesehatan* (BPJS-Kesehatan)[10,11]. Additionally, several new medicine policies were introduced separately by the Ministry of Health to support the JKN-KIS. First, the e-Catalogue was introduced as a national medicine pricing policy. The e-Catalgue

provides a list of medicines with specifications, prices, and suppliers. Second, the national formulary was compiled as a list of medicines covered by the BPJS-Kesehatan[12]. The e-Catalogue and the national formulary have their own respective responsible committees, which were both established in 2013, a year before the implementation of the JKN-KIS. Although the e-Catalogue and the national formulary were established separately, in practice these policies are interrelated. Indonesian healthcare facilities can reimburse medicines listed in the national formulary based on its prices listed in the e-Catalogue[12-14].

According to the national health insurance guidelines of Indonesia, an HTA approach should be used to select a health technology or intervention, including medicines, which will be covered by the BPJS-Kesehatan. This implies that HTA should be used in further developing the e-Catalogue and the national formulary. As a way forward, both may build on the guideline on the implementation of HTA in particular for medicines that the Department of Pharmacy and Medical Devices in the Ministry of Health of Indonesia introduced in 2013[15]. In detail, the national health insurance recommended that the use of HTA is developed and performed by an HTA committee installed by the Ministry of Health[12].

Indeed in 2014, several months after the implementation of the JKN-KIS, the Ministry of Health formed the HTA committee. The committee had eight senior health scientists and six employees of the Ministry of Health, and was supported by 14 secretaries. The tasks of the committee were establishing a policy concept, guidelines, and the HTA committee itself to regulate the implementation of HTA[16]. In 2016, the HTA committee was reformed. The current HTA committee is composed of eight senior health scientists, one employee of the Ministry of Health, and supported by four secretaries. A technical staff with thirteen clinicians, two Ministry of Health employees, and one technician is now added to support the HTA committee tasks. Their current tasks are to define a guideline for HTA implementation, to establish the HTA committee and their work plan, to build a relationship with HTA committees in other countries, to assess the technologies or interventions covered by BPJS-Kesehatan, and to disseminate the results of their assessments[17].

However, although the HTA guideline was published in 2013 and the HTA committee had been installed in 2014, HTA has not been used in the development of the e-Catalogue and the national formulary. This might be one of the reasons why the use of the e-Catalogue and the national formulary could not help to reduce out-of-pocket payments for medicines in Indonesia[18]. In 2014, the out-of-pocket payments comprised approximately half of the total health expenditure in Indonesia, and it has remained at a similar level since[19]. The proportion of out-of-pocket payments for medicines was 70% in recent years[20]. Furthermore, over the same period, the Ministry of Health reported that up to 40% of prescribed medicines were not listed in the NF[21]. Relevant stakeholders were interviewed to provide a better understanding of how to improve the implementation of HTA in Indonesia, with particular attention for suggestions on and barriers perceived regarding the use of HTA in revising the e-Catalogue and the national formulary.

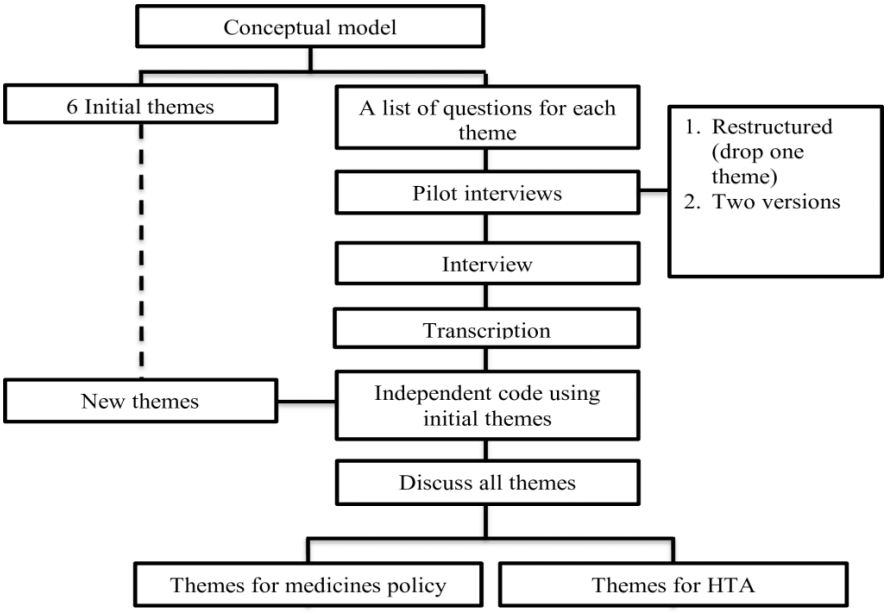
Materials and Methods

Semi-structured interviews with multiple stakeholders were conducted to collect qualitative data. The COnsolidated criteria for REporting Qualitative studies (COREQ) checklist was followed in reporting the results[22].

Study Design and Participants

The process applied in this study can be seen in the flowchart (**Fig 1**). First, a conceptual model (S1 Fig) was developed by RW, MP, WG, TF, and EB, based on a review of WHO documents on UHC, in particular concerning medicine policies and the use of HTA. Based on the conceptual model, initial list of themes and of questions (**S1 Table**) were created to get an overview of the development of medicine policies and the implementation of HTA in Indonesia. With the aim of testing the comprehensibility and appropriateness of the interview protocol (**S1 File**), pilot interviews were conducted with three physicians, three pharmacists, and three patients. After revision based on the pilot, semi-structured interviews were then conducted with various stakeholders. Interviews were planned until saturation was reached.

Figure 1. Research process



A purposive sampling method was used to recruit stakeholders, which consisted of policymakers, medicine suppliers, healthcare providers, and patients in various places of Indonesia. Recruitment criteria were: stakeholders (policy makers, healthcare provider, industry representative) should have at least 5 years of relevant work experience. Physicians were not selected based on their specialization, because HTA would be implemented in the development of the national formulary, which is used by all healthcare providers regardless of their specialization. Both pharmaceutical industries approached produced medicines and medical devices and were responsible for distributing medicine to the healthcare facilities. Patients were selected based on the duration of their health insurance in Indonesia (at least 5 years) and their routine use of medicines (at least 5 years). In order to ensure that these patient criteria were met, participants were recruited from the BPJS-Kesehatan's chronic disease management program (*Program pelayanan penyakit kronis*, Prolanis).

A priory estimation of the number of participants required to reach saturation was made. We estimated that at least twenty-two stakeholders should be approached based on at least two representatives for each group of policy makers, i.e., at least two pharmaceutical industry representatives, at least four interviewees from each group of healthcare providers, and at least four patients. The reason for having more interviewees in the groups of healthcare providers and patients was our interest in the practical issues of the implementation of medicine policy and the difficulties reported for applying HTA for selecting medicine in the medicine policy. Potential participants were approached by email, phone and visit.

Data analysis

All interviews were audiotaped and then transcribed. The transcripts were independently coded by two authors (RW, SI) using MAXQDA version 12.3.2. Directed content analysis [23] was applied to systematically structure the content of the transcripts. The codes were compared, and in case of disagreements, items were discussed with AM, WG, MP, TF, and EB to reach a consensus. Twenty four themes were identified during coding process. The themes were then divided into two categories. The first concerned medicine pricing and reimbursement policy [18] and

the second the implementation of HTA. The current manuscript focused on the six themes (**Table 1**) related to the implementation of HTA.

Table 1. List of themes

No	Themes
1	Attitudes towards HTA implementation
2	Advantages of HTA implementation in the e-Catalogue and the NF
3	Disadvantages of HTA implementation in the e-Catalogue and the NF
4	Barriers to HTA implementation
5	Possible solutions to improve the implementation of HTA
6	Promoting factors of HTA implementation

The transcript interviews from six themes were coded to attain sub-themes. Saturation at the total level was assessed to identify the sub-themes. Saturation was considered to be reached when no new information was generated and when at least three interviewees mentioned the same concern for each sub-theme. These were checked by RW and SI.

Ethical considerations

The main author is Indonesian; therefore, an official research permit is not requested as stated in the relevant regulation of Indonesia". However, a written informed consent (**S2 File**) was obtained from all participants. Before the interviews, all participants understood that their participation was voluntary and that they were free to stop the interview at any time. All participants reviewed and consented to the verbatim transcript of their interview. Additionally, the research plan and the interviews to be conducted were reviewed by the University Medical Center Groningen Ethical Review Board, who deemed the study non-intrusive. Subsequently a formal waiver statement (**S3 File**) was provided, i.e., the study would not need a regular ethical approval.

Results

Participants

Aiming at about 22 final participants, a total of 51 (**S2 Table**) different individuals were approached during the recruitment process. Out of this number, 45 agreed to participate in this research. However, 9 withdrew after receiving the list of questions; another 7 decided to stop their interviews before they were finished, since they experienced difficulties in answering the questions, and were not confident about their answer; Furthermore 4 had no time for an interview, leaving a final number of 25 participants. Notably, this was more than initially aimed at.

Twenty-five participants participated in this research (**Table 2**). They were policy makers (WHO members, HTA Committee, NF Committee and National Health Insurance Agency), a medicine supplier (a pharmaceutical industry representative), healthcare providers (physicians and pharmacists), and users (patients). All participants had the Indonesian nationality, except the WHO members. The policymakers, the pharmaceutical industry representative and healthcare providers each have more than 20 years of work experience in the Indonesian healthcare system. Furthermore, all interviewed patients had been enrolled in health insurance in Indonesia for an average of 11 years at the time of interview.

Table 2. Classification of participants involved

Participants	Gender	Age (Years)	Work experience (Yes)	Years using public health insurance	Professional location
Policymakers					
WHO Members	Male	50	25	NA	Geneva
HTA Committee	Female	53	28	28	Jakarta
HTA Committee	Male	55	30	30	Jakarta
NF Committee	Male	56	31	31	Yogyakarta
JKN-KIS Agency	Female	51	26	26	Jakarta
JKN-KIS Agency	Female	46	21	21	Jakarta
Medicine Supplier					
Pharmaceutical Industry	Male	54	29	29	Jakarta
Healthcare Providers					
Physician	Male	58	33	33	Lombok
Physician	Male	59	34	34	Makassar
Physician	Male	66	41	41	Makassar
Physician	Male	44	19	19	Surabaya
Physician	Male	51	26	26	Jakarta
Physician	Female	54	29	29	Yogyakarta
Pharmacist	Female	53	28	28	Jakarta
Pharmacist	Male	50	25	25	Manado
Pharmacist	Male	39	14	14	Kendari
Pharmacist	Male	42	17	17	Yogyakarta
Pharmacist	Female	51	26	26	Lombok
Pharmacist	Female	40	19	19	Makassar
Users					
Patient	Male	53	NA	8	Makassar
Patient	Male	63	NA	13	Makassar
Patient	Female	59	NA	10	Makassar
Patient	Male	57	NA	8	Makassar
Patient	Female	63	NA	12	Makassar
Patient	Male	63	NA	13	Makassar

Interviews and analysis of transcripts

Semi-structured interviews were conducted face to face with 16 participants and through video calls with 9 participants between August 2016 and April 2017. One interview was conducted in English, while all others were in Bahasa Indonesia. The average time spent on each interview was circa one hour.

Transcripts from the themes for HTA were checked to obtain sub-themes (**S3 Table**). For all six themes, more than three interviewees mentioned the same concern on each sub-theme. It means that saturation could be confirmed at the total level. In table S3 we summarize the answers by respondent group, to make it easier for readers to understand the main concerns of each stakeholder group. The complete statement per theme can be found at raw materials (**S4 Table**).

Findings per theme

Theme 1: Attitudes towards HTA implementation

All stakeholders demonstrated positive attitudes towards applying HTA to the development of the e-Catalogue and the NF. The main reason expressed for this attitude was the necessity of having appropriate medicine policies to support the JKN-KIS program in achieving UHC, in particular, reducing out-of-pocket payments for medicines. Moreover, participants perceived the advantages would outweigh the disadvantages.

> *"If the HTA is applied to the NF or e-Catalogue I am very amenable. This will definitely be very good and provide great benefits"* **[Physician 5]**

Theme 2: Advantages of HTA implementation in the e-Catalogue and the NF

Stakeholders recognized that the main advantage of HTA is to provide scientific evidence for decision makers to assess the value of a medicine. Additionally, the participants identified various other benefits when HTA would be implemented in the e-Catalogue and the NF.

> *"The money allocated for the health sector is limited, especially for medicines. So, we can convince the government that more money should be allocated for medicines"* **[Policymaker 6]**

The pharmaceutical industry representative mentioned that HTA would provide a ground for fair pricing in the e-Catalogue. Thus, pharmaceutical industries would not arbitrarily adapt their prices.

> *"HTA can provide the rational price for bidding the medicines. Now, the pharmaceutical industry can bid the medicines as low as possible"* **[Pharmaceutical Industry]**

The policy makers, healthcare providers, and patients mentioned the use of HTA would reassure all stakeholders that the medicines listed in the NF were the best choice of medication. This would convince the government to allocate the money for providing the medicines listed in the NF, the physicians to prescribe the medicines listed in the NF, and also the patients to consume the medicines listed in the NF.

> *"The advantage is that we may not doubt anymore about taking the medicine listed in the NF"* **[Patient 1]**

Theme 3: Disadvantages of HTA implementation in the e-Catalogue and the NF

Among all interviewees, only a few could mention disadvantages of HTA implementation in the e-Catalogue and the NF. The most frequently mentioned disadvantage was the cost of developing the e-Catalogue and the NF probably would increase, in particular to pay HTA experts. In addition, complicated bureaucracy and lengthy processes for renewing the medicines listed in the e-Catalogue and the NF were also mentioned by the policy makers and healthcare providers.

> *"People could say that this is too heavy or too bureaucratic, you need an excessively lengthy process for this"* **[Policymaker 1]**

Theme 4: Barriers to HTA implementation

The participants identified various barriers that are currently hampering the implementation of HTA. The first barrier mentioned by all stakeholder categories, except the patients, was a lack of capability and a lack of capacity of local human resources. The reasons for this as explained by several interviewees were that HTA is a new science in Indonesia, and a lack of HTA departments, training and associations.

> *"The science of HTA is still very new in Indonesia. Honestly, there are still many health workers and maybe including me who do not understand the application."***[Pharmacist 5]**

A second barrier mentioned by all categories of stakeholders, except the pharmaceutical industry representative, was a lack of incentives. The stakeholders considered that currently little resources are available for paying the HTA experts, holding HTA seminars, and performing HTA research.

> *"There is a significant financial problem for the experts, since the HTA Committee still depends on the state budget and the standard fees established by the Ministry of Finance must be adhered to. We cannot give the fee according to their (HTA experts) expertise because there is a maximum salary that can be awarded when using the state budget"*. **[Policymaker 3]**

A third barrier mentioned by the policy makers pharmaceutical industry representative and healthcare providers was a lack of a clear framework of how to implement using HTA results in the medicine policy, in particular in the e-Catalogue and the NF. These interviewees mentioned that a clear framework is needed since multiple professions have to cooperate to initiate HTA, perform HTA, assess and appraise HTA results, and translate findings into policy advise.

> *"We do not yet have a clear path of how to apply HTA. Moreover, HTA requires a variety of professions. This will create a conflict of interest. If there are no clear guidelines, all will be based on the point of view of each profession".* **[Pharmaceutical Industry]**

A fourth barrier mentioned by the policy makers and healthcare providers was insufficient data for conducting HTA studies. The HTA committee members interviewed perceived the insufficient data was caused by difficulties to access data on the national scale. National data gathering is managed by the JKN-KIS agency. The JKN-KIS agency representative explained that the insufficient data was caused by unclarities regarding the data needed for conducting HTA studies. Furthermore, the health care providers also mentioned that the healthcare registry data, for instance, individual patient data, have not been integrated in the national scale.

> *"The number of provinces in Indonesia makes it difficult to integrate all the data that could be used for HTA studies, so, we still need time to collect the data needed by the HTA researchers"* **[Policymaker 6]**

Theme 5: Possible solutions to improve the implementation of HTA

The participants provided a variety of possible solutions to address the barriers hampering the implementation of HTA. The policy makers indicated a necessity to establish a good network to build up the capacity. For instance, students and researchers could be endorsed to conduct HTA studies using Indonesian data. Currently, the Ministry of Health only depends on the state budget to establish the HTA committee and to build the capacity. Pharmaceutical industries could be encouraged to provide additional means.

> *"The government must obtain alternative funding instead of depending on the state budget to implement HTA. I think the pharmaceutical industry can actually be asked to provide additional income in order to finance experts or researchers of HTA studies".* **[Policymaker 2]**

The pharmaceutical industry representative suggested the creation of a clear framework for performing HTA implementation. The healthcare providers recommended that the government would provide more training and seminars to improve the capability of human resources regarding HTA. The healthcare professionals similarly suggested opening more HTA departments in universities in Indonesia. Finally, patients expected the government and all stakeholders to have a good collaboration in terms of introducing the implementation of HTA in Indonesia.

> *"The government through the health ministry should establish guidelines to have a clear path to implement HTA"* **[Pharmaceutical Industry]**
>
> *"The government should encourage universities to open HTA departments. So, we can learn the topics of HTA in a good curriculum".* **[Pharmacist 1]**
>
> *I hope all stakeholders can work together and find a good solution to start the implementation of HTA in Indonesia".* **[Patient 6]**

Theme 6: Promoting factors for the implementation of HTA

The participants identified several promoting factors for the implementation of HTA. First of all, the main factor mentioned by all stakeholder's category was that the JKN-KIS aims to achieve UHC. Several stakeholders perceived that the use of HTA is suitable for countries that are on their way to implement UHC. A second promoting factor mentioned was that the use of HTA is already in the regulation for

implementing JKN-KIS, in particular to select medicines which will be covered by the BPJS-Kesehatan. Therefore, the use of HTA is mandatory in developing the list of medicines in the e-Catalogue and the NF. A third promoting factor was the use of the current e-Catalogue and the NF without HTA implementation have not helped sufficiently to reduce out-of-pocket payments for medicines.

> *"The supporting factor is that we are implementing an international scale program, which is Universal Health Coverage. The HTA program is highly recommended World Health Organization for countries implementing UHC program."* **[Physician 6]**
>
> *"The regulation of Indonesia stated that HTA should be conducted for selecting the healthcare services needed. Indonesia is lucky since it has a legal aspect, whereas Vietnam does not have this. In some European countries it is also not present".* **[Policymaker 2]**
>
> *"We need a list of medications which were well selected at the NF. This was to avoid the doctors prescribed medicines not listed in the NF and also to prevent patients from spending money because they have to buy medicines that are not covered by BPJS Kesehatan".* **[Pharmacist 5]**

Discussion

This study provides insight into the current implementation of HTA in Indonesia in the development of the e-Catalogue and the National Formulary as medicines policies, as perceived by multiple stakeholders. To the best of our knowledge, no previous interview-based studies on this topic were performed in South East Asia. All interviewees showed a positive attitude towards the application of HTA to the e-Catalogue and the NF. The interviewees expected HTA could optimize the use of the e-Catalogue and the NF to reduce out-of-pocket payments and, subsequently, to achieve UHC in Indonesia. Furthermore, the stakeholders identified the advantages of applying HTA to both the e-Catalogue and the NF were greater than the disadvantages. However, interviewees mentioned that the application of HTA has the potential to increase costs for the development of the e-Catalogue and the NF. Specifically, this study clarifies the barriers, possible solutions, and facilitators of HTA implementation.

Interestingly, some interviewees perceived that the use of HTA would increase the cost for developing the e-Catalogue and the NF. However, other participants mentioned that the use of HTA for the e-Catalogue and the NF could improve efficiency. Our previous study[18] has revealed that the e-Catalogue and the NF have not been fully utilized in the healthcare facilities and were often ignored by stakeholders. This implies that unnecessary spendings have been allocated for producing these two medicine policies. For the e-Catalogue, HTA might support the setting of minimum prices as one of the problems mentioned was that the final tendered prices of medicines were too low and might jeopardize quality and distribution of medicines. Such prices would then reflect reasonable price levels for each medicine, in terms of costs per quality adjusted life years gained[24]. In addition, interviewees mentioned that the use of HTA in the NF might help to provide transparency and evidence for selecting medicines listed in the NF, and that this could improve its acceptance and use by stakeholders. Several LMICs aiming to achieve UHC have to consider a way to limit or choose the available healthcare services and HTA is one of the tools to support reimbursement package decision making. Many exemplary countries, such as Thailand, China, and Australia show

how the use of HTA is helpful in selecting the medicines listed in their medicine reimbursement list. Thus, a more effective way of achieving UHC is achieved[6].

Several barriers to implement HTA were identified and reported in the results. The two most important barriers mentioned were a lack of local human resources and a lack of financial incentives. previous studies[25] based on surveys stated that these barriers were the major barriers in 19 LMICs, including Vietnam as Indonesia's neighboring country. In addition, for other neighboring countries, such as Philipines and Malaysia, capacity building and financial incentives were also identified as significant barriers for implementing HTA in their medicine policies[26-28]. In the current study, the interviewees offered several possible solutions to overcome these obstacles. An interesting solution suggested by the NHI agency was that the HTA committee could establish a network with other countries that have a well-established system, and with international HTA organizations. In response to financial barriers, the authors support a solution suggested by the HTA committee that the Government of Indonesia could provide an alternative funding instead of depending on the state budget. The interviewees recognized the need of HTA but also wondered how it should be funded. We think the implementation as achieved by the HTA committee of Thailand may serve as an example. The Committee obtains funding from the Thai Health Promotion Foundation, an institution established by the Ministry of Health of Thailand to collect health funding through two percents surcharge levied on the excise tax of alcohol and tobacco. This institution also obtains its funding from pharmaceutical companies and international HTA agencies[29].

The main important factor mentioned to support HTA implementation in the e-Catalogue and the NF was a mandate in the Presidential Decree[30], which stated that the development of medicine policies must be based on the HTA study. This implies the HTA must be applied in the e-Catalogue and the NF development. Based on a previous international study[31], this implication can lead to a continuous development of the capacity building for local human resources.

Conducting interviews allowed the researcher to obtain detailed information about personal feelings, perceptions and opinions from the participants

indepedently from other group members. Moreover, all ambiguities and incomplete answers could be clarified and followed up. Several steps were taken to ensure a good research practice during the data compilation and analysis stages. The sampling processs used to select participants and the interview guide were compared with recommendations published in the COREQ[22].

Though a variety of stakeholders were interviewed in this study, not all groups of stakeholders were equally large and it turned out hard to find industry representatives willing to participate. Notably, only one pharmaceutical industry representative agreed to participate. Nonetheless, the interviewee was relatively experienced and was a leader in several pharmaceutical associations in Indonesia.

While saturation was reached at the level of the total group, it could not be ensured for smaller groups of stakeholders, namely industry and policy makers. Also, this research contained interviews with a specific group of patients, namely from the Prolanis. The main reason for this was that participants from this group were relatively easy to find and recruit. These patients affiliated to the Prolanis group were considered as being able to provide more information than other patients since they had already routinely consumed medicines and had actively used public health insurance in Indonesia for a significant time period. It is relevant to note that quite a few people did not feel comfortable to participate or withdrew their consent after having seen the questions for the interview. This may indicate that a substantial part of stakeholders is not very familiar with the concepts discussed during the interviews and/or considers the topics as hard to discuss.

Recognizing the current barriers and facilitators identified to apply HTA in the development of the e-Catalogue and the national formulary could assist decision makers in developing a blueprint for the further implementation of HTA in Indonesia. This could also be relevant for international policymakers in other LMICs with similar characteristics and ambition to achieve UHC.

Conclusions

Several barriers are currently hampering the implementation of HTA to support medicine pricing and reimbursement policies in Indonesia. However, solutions for these issues are under consideration and facilitators do exist. The major barriers to the implementation of HTA are a lack of capacity of local human resources and a lack of (financial) incentives. Possible solutions to address these issues would be to establish a network with other countries that have a well-established system, and with international HTA organizations. A major opportunity to support the implementation of HTA in the e-Catalogue and the NF is the existing legal framework to implement HTA in medicine policies of the JKN-KIS program in Indonesia.

Acknowledgments

The authors would like to thank all stakeholders who participated in this study.

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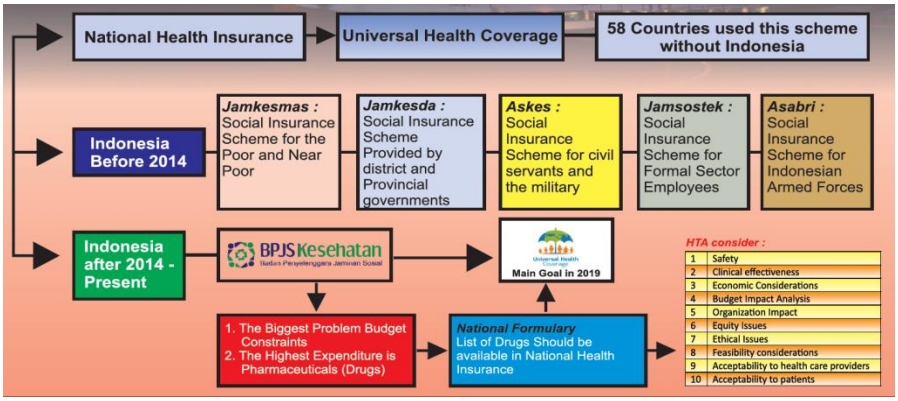
Supporting Information

S1 Fig. Conceptual framework



Explanation of conceptual framework:

Many countries aim to reform their national health insurance to reach universal health coverage. Nowadays, 58 countries are using universal health coverage besides Indonesia. Before 2014, various health insurance schemes covered health insurance for Indonesian society. As of 2014, all these schemes were integrated and organized under one agency called BPJS-Kesehatan. The main goal of this insurance is to achieve universal health coverage by 2019. The problem with BPJS-Kesehatan was budgetary constraints, with the highest expenditure being pharmaceuticals. The national formulary was used to organize medicines. HTA has not yet been applied in the national formulary, while many UHC countries do.

S1 Table. Initial list of themes and of questions

NO	THEMES	NO	QUESTIONS
1	The development of medicine policy and national health insurance	1	Do you know how long the HTA Committee, NF Committee, and NHI Agency have existed?
		2	How many committee members?
		3	What are their professions?
		4	What are their duties?
		5	Why do they exist?
		6	What is their function?
		7	What is their role in supporting UHC?
		8	How is the NHI different from previous health insurance (Askes, Jamkesmas, etc)?
		9	How many people are covered by the NHI Agency currently?
2	Medicines policy for UHC	10	What medicines policy or policies should be created to support UHC?
		11	Are you involved in creating the NF and other medicines policies to support UHC?
3	Users Perspective	12	Do you know how the National Formulary is compiled?
		13	Do you agree with the NF?
		14	Do you have policy recommendations to maximize the use of HTA?
		15	Do you have other policy recommendations for prescribing drugs?
4	Obstruction and promoting factors of HTA	16	What is/are the advantage(s) using HTA in medicines policy?
		17	What is/are the disadvantage(s) using HTA in medicines policy?
		18	What is/are the facilitator(s) implementing HTA in medicines?
		19	What is/are the barrier(s) implementing HTA in medicines?
		20	What should other stakeholders do to solve them? And which ones?
		21	What should the government do?
5	The biggest burden of disease and medicine expenditure	22	What is the most widespread disease in Indonesia?
		23	How much money is allocated for medicines in the national health system?
		24	What medicines are allocated more money? (Why?)
6	Prescriptions not in NF	25	Have you ever received prescriptions for drugs not in the NF (How frequently and why)?
		26	Which medicines do you receive most often that are in the NF?
		27	Do you agree when doctors prescribe medicines not in the NF? Why?

S2 Table. Overview of the recruitment process

Types of stakeholders	Send letter	Responds	Interviews	Cancel after receiving list of questions	Stop the interview	No times available	Not response
WHO members	2	2	1	0	0	1	0
HTA committee	3	2	2	0	0	0	1
NF committee	3	1	1	0	0	0	2
NHI Agency	3	3	2	0	0	1	0
Pharmaceutical Industry	4	3	1	0	0	2	1
Physicians	12	10	6	1	3	0	2
Pharmacist	15	15	6	5	4	0	0
Patients	9	9	6	3	0	0	0
Total	**51**	**45**	**25**	**9**	**7**	**4**	**6**

S3 Table. Saturation checklist on sub-theme

No	Themes	Policy Makers						Medicine Supplier	Physicians						Pharmacist						Patients					
		1	2	3	4	5	6	1	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6
1	**Attitude**																									
	Agree	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
2	**Advantages**																									
	To Provide scientific evidence	+	+	+	+	+	+	+	+	+		+	+	+			+	+								
	To Provide a ground for fair pricing in the e-Catalogue							+		+				+		+			+					+		
	To reassure the medicines listed in the NF were the best choice	+	+	+	+		+		+	+	+	+	+	+	+	+	+		+	+	+	+	+		+	+
3	**Disadvantages**																									
	Increase the cost of developing the e-Catalogue and the NF	+									+	+		+			+	+	+				+			
	Complicated bureaucracy	+		+			+																			
	Lengthy Process for renewing medicines listed in the e-Catalogue and the NF	+		+			+		+	+	+			+			+									
	No disadvantage		+		+	+		+							+	+				+	+	+			+	+
4	**Barriers**																									
	A lack of capability of local human resources	+	+	+	+	+	+	+	+		+	+	+	+	+			+	+	+						
	A lack of financial incentives	+	+	+	+	+	+					+					+				+	+	+	+	+	+
	A lack of a clear framework	+	+				+	+		+				+	+	+		+								
	Insufficient data	+	+				+								+			+	+							
5	**Possible solutions**																									
	To establish (inter)national network to build up capacity	+	+	+	+		+			+		+		+							+	+	+	+	+	+
	To introduce a clear HTA framework	+	+			+	+	+	+		+		+	+		+	+	+	+	+	+					
	To open HTA department, training, and association	+	+	+	+					+	+	+	+	+	+					+						
6	**Facilitating factors**																									
	The ambition to achieve UHC	+	+	+		+	+		+	+	+	+	+	+			+		+	+	+		+			
	The presence of legal framework to implement HTA in the e-Catalogue and the NF	+	+	+	+	+	+					+			+	+		+	+	+					+	+
	The demand for appropriate medicine policies.	+	+					+														+		+		

S4. Table. Raw materials

Raw material can be found in this link below:
https://doi.org/10.1371/journal.pone.0225626.s005

or in this quick response code below

S1 File. Interview protocol

List of Questions for participants (excluding patients)

Key terms:	
GOI	= Government of Indonesia
HTA	= Health Technology Assessment
JKN-KIS	= a National Health Insurance scheme of Indonesia
UHC	= Universal Health Coverage

1. What do you know about the JKN-KIS program? **Which points can you explain:**
    a. Implementing Agency;
    b. When executed;
    c. Implementation goals;
    d. Other personal information according to participants?
2. As far as you know, what public health insurance programs have been implemented prior to the implementation of the JKN-KIS program?
    a. Implementing Agency;
    b. The policy/program that they imposed to control medicines?
3. Do you know why all public health insurance programs are integrated into JKN-KIS?
4. What are the medicine policies/programs imposing on the JKN-KIS?
    a. The role or the functions of the policies
    b. What are the policy-making processes?
    c. Are you involved in the policy-making process?
    d. Who is involved in the policy-making process?
    e. Do you agree with the program/policies?
    f. Do you think there is/are stakeholder(s) harmed by that policy? For example, doctors, pharmacists, the pharmaceutical industry, patients, etc.
    g. Do you think the policy is based on the latest scientific evidence?
    h. In your opinion, are there any other policy proposals that should be applied?

5. What do you know about the HTA?
    a. Implementing Agency;
    b. When executed;
    c. Implementation goals;
6. Do you think the HTA should be applied to the medicine policies on the JKN-KIS?
7. In your opinion, what are the advantages and disadvantages of using HTA in medicine policies on JKN-KIS?
8. In your opinion, what are the supporting and inhibiting factors for the use of HTA on medicine policies in JKN-KIS?
9. In your opinion, what solutions should be found to implement the HTA on medicine policies in JKN-KIS?
    a. What should be done by all stakeholders (policymakers, doctors, pharmacists, drug companies, patients, etc.)
    b. What should be done by the GOI?
10. Have you ever found prescriptions not in the medicine policies on JKN-KIS?
    a. Do you know why this occurred?
    b. Do you agree with prescriptions not being in the medicines policy?
    c. What medicines are most commonly prescribed that are not part of the policies of JKN-KIS?
    d. Do you have any suggestions to overcome this?
11. Do you know how much money is allocated for medicines to support the JKN-KIS program?
    a. Do you know which drugs are allocated the largest budget?
12. Do you know what is the most widespread disease in Indonesia?
    a. Do you know how much money is allocated to cope with this disease?
13. Do you have other comments regarding this research?

List of Questions for Participants (excluding patients) in

Bahasa

Pengertian Istilah:
HTA = *Health Technology Assessment*/ Penilaian Teknologi Kesehatan;
JKN-KIS = Program Jaminan Kesehatan Nasional di Indonesia;
UHC = Universal Health Coverage/ Cakupan Perlindungan Semesta.

1. Apa yang anda ketahui tentang JKN-KIS. **Point yang dapat anda jelaskan yaitu**:
   a. Instansi apa yang melaksanakan?
   b. Kapan mulai dilaksanakan?
   c. Apa tujuan dilaksanakan?
   d. Informasi lain yang dianggap perlu disampaikan dari partisipan
2. Sejauh yang anda ketahui, program jaminan kesehatan publik apa saja yang dilaksanakan sebelum diberlakukannya JKN-KIS?
   a. Instansi apa yang melaksanakan?
   b. Apakah anda tahu kebijakan/ program apa yang mereka terapkan untuk mengontrol obat?
3. Apakah anda tahu, mengapa seluruh program jaminan kesehatan publik berintegrasi ke JKN-KIS?
4. Apa sajakah kebijakan/ program yang sudah diberlakukan oleh pemerintah pada program JKN-KIS?
   a. Apakah anda tahu fungsi kebijakan/ program tersebut?
   b. Apakah anda tahu bagaimana proses pembuatan kebijakan tersebut?
   c. Apakah anda terlibat dalam proses pembuatan kebijakan tersebut?
   d. Siapa-siapa saja yang terlibat dalam proses pembuatan kebijakan tersebut?
   e. Apakah anda setuju dengan kebijakan tersebut? Mengapa?
   f. Menurut anda, adakah stakeholders (Dokter, Apoteker, Perusahaan obat, pasien, dll) yang dirugikan dengan kebijakan tersebut?
   g. Menurut anda, apakah kebijakan tersebut telah melalui bukti ilmiah mutakhir?
   h. Menurut anda, adakah usulan kebijakan lain yang sebaiknya diterapkan?

5. Apa yang anda ketahui tentang HTA?
    a. Instansi apa yang melaksanakan?
    b. Kapan mulai dilaksanakan?
    c. Apa tujuan dilaksanakan?
6. Menurut anda, apakah HTA sebaiknya diterapkan pada kebijakan obat yang sudah diterapkan pemerintah untuk mendukung JKN-KIS?
7. Menurut anda, apa keuntungan dan kerugian menggunakan HTA pada kebijakan obat yang sudah diterapkan pemerintah?
8. Menurut anda, apa faktor pendukung dan faktor penghambat menggunakan HTA pada kebijakan obat yang sudah diterapkan pemerintah?
9. Menurut anda, soulusi apa yang sebaiknya dilakukan untuk melaksanakan HTA pada kebijakan obat yang sudah diterapkan pemerintah?
    a. Apa yang sebaiknya dilakukan oleh para stakeholders (pembuat kebijakan, dokter, apoteker, perusahaan obat, pasien, dll)?
    b. Apa yang sebaiknya dilakukan oleh pemerintah?
10. Pernahkah anda menemukan peresepan obat di luar kebijakan obat yang sudah diterapkan pemerintah?
    a. Apakah anda setuju dengan peresepan obat diluar kebijakan obat yang sudah diterapkan pemerintah?
    b. Obat apa yang paling sering diresepkan diluar kebijakan obat yang sudah diterapkan pemerintah?
    c. Apakah anda tahu, bagaimana cara mengatasi hal tersebut?
11. Apakah anda tahu berapa banyak anggaran belanja obat yang dialokasikan untuk mendukung JKN-KIS?
    a. Apakah anda tahu obat apa yang mendapatkan anggaran terbesar?
12. Apakah anda tahu penyakit yang terbesar di Indonesia?
    a. Apakah anda tahu berapa banyak anggaran untuk obat yang dialokasikan untuk mengatasi penyakit tersebut?
13. Apakah ada komentar lainyang ingin anda sampaikan terkait penelitian ini?

A List of Questions for Patients

Key terms:	
GOI	= Government of Indonesia
HTA	= Health Technology Assessment
JKN-KIS	= a National Health Insurance scheme of Indonesia
UHC	= Universal Health Coverage
NF	= National Formulary

1. Do you know about JKN-KIS, which is part of BPJS-Kesehatan? Could you explain briefly it?
2. Are you a participant in JKN-KIS?
3. When were you be a participant in JKN-KIS?
4. What health insurance did you use before JKN-KIS?
5. For how long were you a participant in that insurance?
6. Are you currently taking any medication?
    a. When was the last time you took the drugs?
    b. What drugs did you take?
7. Did you also take that medicine when using your previous insurance?
8. Do you feel a difference when taking medication of JKN-KIS compared with medication of your previous health insurance?
    a. Which one is cheaper?
    b. Which are more efficacious?
    c. Which one do you like, and think is better?
9. Is there a difference, do you feel, in terms of service between JKN-KIS and your previous health insurance?
    a. Are there differences when seeing doctors?
    b. Is there a difference when conducting laboratory checks or other checks?
10. Do you know about UHC? Could you explain briefly what you know?
    a. Do you agree with the GOI's target of reaching UHC in 2019?
    b. Do you think it can be achieved?
    c. Are there any suggestions from you in order to achieve the UHC?
11. Do you know about NF? Could you explain briefly about that?
    a. Do you know how NF is created?

b. Do you agree with NF?
c. What medications do you often receive which are in NF?
d. Have you ever received prescriptions not in the NF? How often? Why?
e. Do you agree with prescriptions not in the NF? Why?
f. Do you have a policy recommendation in prescriptions?

12. Do you know about HTA? Could you explain briefly what you know?
    a. Do you think the HTA can be used for medicines policy in Indonesia?
    b. In your opinion, what is the advantage of using HTA in determining the choice of medicines?
    c. In your opinion, what are the disadvantages of using HTA in determining the choice of medicines?
    d. In your opinion, what are the promoting factors in implementing an HTA for drug selection?
    e. In your opinion, what are the obstacles in implementing an HTA for drug selection?
    f. In your opinion, what should be done by stakeholders to resolve this?
    g. In your opinion, what should the government do?
13. Do you have suggestions for improving medicines policy?
14. Do you have other comments related to this research?

A List of Questions for Patients in Bahasa

1. Apakah anda tahu tentang jaminan kesehatan nasional yang dikelola oleh BPJS-Kesehatan? Bisakah anda Jelaskan sedikit tentang hal itu?
2. Apakah anda anggota BPJS-Kesehatan?
3. Kapan anda mulai menjadi anggota BPJS-Kesehatan?
4. Asuransi apa yang anda gunakan sebelum menjadi anggota BPJS-Kesehatan ?
5. Berapa lama anda menjadi anggota asuransi tersebut?
6. Apakah anda mengkonsumsi obat saat ini?
    a. Kapan terakhir kali anda mengkonsumsi obat?
    b. Obat apa?
7. Apakah obat tersebut juga anda konsumsi dengan menggunakan asuransi yang sebelumnya?
8. Apakah ada perbedaan yang anda rasakan ketika menggunakan obat dari BPJS dengan obat dari asuransi anda sebelumnya?
    a. Yang mana yang lebih murah?
    b. Yang mana yang lebih berkhasiat?
    c. Yang mana yang anda suka dan anggap lebih baik?
9. Apakah ada perbedaan yang anda rasakan dari sisi pelayanan pada Asuransi BPJS dan Asuransi yang anda gunakan sebelumnya?
    a. Apakah ada perbedaan ketika bertemu dengan dokter?
    b. Apakah ada perbedaan ketika melakukan cek laboratorium atau pemeriksaan lainnya?
10. Apakah anda tahu tentang Univeral Health Coverage (UHC)/ Jaminan kesehatan secara menyeluruh? Bisakah anda Jelaskan sedikit tentang hal itu?
    a. Apakah anda sependapat dengan pemerintah Indonesia yang ingin mencapai UHC di tahun 2019?
    b. Apakah anda pikir itu bisa dicapai?
    c. Apakah ada saran dari anda untuk mencapai UHC tersebut?
11. Apakah anda tahu tentang Formularium Nasional (Fornas)?
    a. Apakah anda tahu bagaimana Fornas dibuat?
    b. Apakah anda setuju dengan Formularium Nasional?

c. Obat apa yang sering anda terima yang ada di dalam Fornas?
d. Pernakah anda menerima obat di luar Fornas? Seberapa sering? Kenapa?
e. Apakah anda setuju ketika dokter menuliskan obat diluar formularium nasional? Kenapa?
f. Apakah anda memiliki rekomendasi kebijakan dalam penulisan obat?

12. Apakah anda tahu tentang Health Technology Assessment (HTA) / Penilaian Teknologi Kesehatan? Bisakah anda Jelaskan sedikit tentang hal itu?
    a. Menurut anda, apakah HTA dapat digunakan untuk kebijakan obat di Indonesia?
    b. Menurut anda, apa keuntungan menggunakan HTA dalam menentukan pilihan obat?
    c. Menurut anda, apa kerugian menggunakan HTA dalam menentukan pemilihan obat?
    d. Menurut anda, apa faktor pendukung dalam menjalankan HTA pada pemilihan obat?
    e. Menurut anda, apa faktor penghambat dalam menjalankan HTA pada pemilihan obat?
    f. Apa yang harus dilakukan oleh pemangku kebijakan untuk menyelesaikan itu?
    g. Menurut anda, apa yang harus dilakukan oleh pemerintah?
13. Apakah anda memiliki saran untuk meningkatkan kebijakan obat?
14. Apakah anda memiliki saran untuk penelitian ini?

S2 File. Informed consent

Lembar penjelasan dan persetujuan kepada partisipan

Peluang dan tantangan kebijakan obat pada program JKN-KIS untuk mencapai Cakupan Perlindungan Semesta / *Universal Health Coverage* (UHC)

Saya Riswandy Wasir, Mahasiswa Program Pascasarjana (S3) Departemen Epidemiologi, Univerity Medical Center Groningen (UMCG), University of Groningen, Netherlands. Saat ini saya sedang melakukan penelitian yang berjudul "peluang dan tantangan kebijakan obat pada program JKN-KIS untuk mencapai cakupan perlindungan semesta".

Pemerintah Indonesia telah menerapkan skema asuransi kesehatan nasional (JKN-KIS) yang terintegrasi dimulai pada tahun 2014. Asuransi kesehatan yang dikelolah oleh BPJS-Kesehatan dimaksudkan sebagai pengganti seluruh asuransi kesehatan publik sebelumnya. Peta jaminan kesehatan nasional yang dirilis oleh pemerintah menyatakan bahwa program JKN-KIS diupayakan mencapai cakupan perlindungan semseta/ *Universal Health Coverage* (UHC) pada tahun 2019. Organisasi Kesehatan Dunia/ *World Health Organization* (WHO) menyatakan bahwa bukan hanya kepesertaan yang menjadi indikator tercapainya cakupan perlindungan semesta, tetapi juga kualitas pelayanan.

Berbagai upaya telah dilakukan oleh pemerintah dan para pemangku kebijakan untuk meningkatkan mutu pelayanan JKN-KIS. Pada sektor obat, pemerintah Indonesia telah menerapkan formularium nasional. Manfaat Fornas yaitu sebagai acuan penetapan penggunaan obat dalam JKN-KIS, serta meningkatkan penggunaan obat yang rasional, dapat juga mengendalikan mutu dan biaya pengobatan, serta mengoptimalkan pelayanan kepada pasien Namun, Hasil evaluasi awal yang dilakukan oleh Direktorat Jenderal Bina Farmasi dan Alat Kesehatan (Dirjen Binfar dan Alkes) memperlihatkan bahwa kesesuaian obat yang digunakan di rumah sakit dengan formularium nasional berkisar antara 60 – 86 %. Hal ini memperlihatkan bahwa masih ditemukan *cost-sharing*, suatu kondisi dimana peserta JKN-KIS harus mengeluarkan biaya untuk pembayaran pelayanan kesehatan

termasuk obat. Salah satu Indikator tercapainya cakupan perlindungan semesta (UHC) menurut WHO adalah tidak adanya *cost-sharing*.

Kami, melakukan penelitian ini untuk mengidentifikasi peluang dan tantangan kebijakan obat pada program JKN-KIS untuk mencapai cakupan perlindungan semesta. Penelitian ini akan melibatkan beberapa pemangku kepentingan yang dianggap memiliki peran dalam membuat kebijakan, mengimplementasikan serta merasakan dampak dari kebijakan tersebut antara lain sebagai berikut:

No	Partisipan	Peran
1	Organisasi Kesehatan Dunia (WHO)	Pembuat Kebijakan skala Internasional
2	Komite HTA	Pembuat kebijakan skala nasional
3	Komite Formularium Nasional	Pembuat kebijakan skala nasional
4	BPJS-Kesehatan	Penyelenggara JKN-KIS dan Pembayar
5	Perusahaan Farmasi	Pemasok obat
6	Dokter	Penyedia pelayanan kesehatan
7	Apoteker	Penyedia pelayanan kesehatan
8	Pasien	Peserta JKN-KIS/ Pengguna

Penelitian akan dilaksanakan dengan metode wawancara bebas terpimpin (*semi-structured interview)*. Daftar pertanyaan, surat kesediaan berpartisipasi (*informed consent*), dan pedoman wawancara akan diberikan oleh peneliti kepada partisipan sehari sebelum wawancara atau pada waktu yang telah ditentukan bersama. Durasi waktu pada saat melaksanakan wawancara mendalam yaitu sekitar 1 (satu) jam.

I. Kesukarelaan untuk ikut penelitian

Bapak/ Ibu/ Saudara bebas memilih keikutsertaan dalam penelitian ini tanpa ada paksaan. Bila bapak/ ibu/ saudara sudah memutuskan untuk ikut dapat juga mengundurkan diri setiap saat tanpa dikenai denda ataupun sanksi apapun.

J. Prosedur Penelitian

Apabila Bapak/ Ibu/ Saudara bersedia berpartisipasi dalam penelitian ini, diminta menandatangani lembar persetujuan ini rangkap dua, satu untuk Bapak/ Ibu/ Saudara simpan, dan satu untuk peneliti. Prosedur selanjutnya adalah :

5. Penelitian akan dilaksanakan dengan metode wawancara terpimpin (*semi-structured Interview*) sesuai dengan kesepakatan dan kenyamanan bapak/ ibu/ saudara menggunakan alat perekam.
6. Peneliti akan mentranskrip hasil wawancara setelah melaksanakan interview dengan partisipan.
7. Hasil transkrip akan diperlihatkan kembali kepada partisipan untuk mengklarifikasi hasil wawancara.
8. Hasil transkrip yang telah disepakati antara peneliti dan partisipan akan diproses oleh peneliti beserta tim peneliti lainnya untuk kemudian dijadikan data kualitatif yang akan di publikasi.

K. Kewajiban partisipan

Sebagai partisipan, Bapak/Ibu/Saudara berkewajiban mengikuti aturan atau petunjuk penelitian seperti yang tertulis di atas. Bila ada yang belum jelas, Bapak/ Ibu/ Saudara bisa bertanya lebih lanjut kepada peneliti.

L. Risiko

Penelitian ini tidak menyebabkan risiko yang berbahaya, karena peneliti tidak melakukan intervensi apapun. Risiko ketidaknyamanan atau dampak yang mungkin akan diterima yaitu merasa bosan dengan banyaknya pertanyaan- pertanyaan dari peneliti dan kerugian waktu selama diwawancarai oleh peneliti.

M. Manfaat dan Keuntungan

Manfaat dan keuntungan yang bapak/ ibu/ saudara dapatkan adalah kesempatan dan kebebasan untuk menjelaskan mengenai apa yang anda rasakan terhadap kebijakan obat pada program JKN-KIS. Penelitian ini nantinya akan diupayakan menjadi masukan terhadap pengambil kebijakan dalam meningkatkan sektor kesehatan nasional.

N. Kerahasiaan

Semua informasi yang berkaitan dengan identitas partisipan akan dirahasiakan dan hanya akan diketahui oleh peneliti. Data hasil penelitian akan disimpan dan didokumentasikan oleh peneliti serta hanya digunakan untuk kepentingan ilmiah. Hasil penelitian akan dipublikasikan tanpa identitas partisipan.

O. Kompensasi

Bapak/ ibu/ saudara akan mendapatkan souvenir sebagai wujud terima kasih peneliti atas partisipasinya dalam penelitian ini.

P. Informasi Tambahan

Bapak/ ibu/ saudara diberi kesempatan untuk menanyakan semua hal yang belum jelas sehubungan dengan penelitian ini. Bila sewaktu-waktu terjadi kekeliruan atau membutuhkan penjelasan lebih lanjut, Bapak/ ibu/ saudara dapat menghubungi Riswandy Wasir pada no HP: +62-81225835007 atau bisa juga dengan mengirimkan email: riswandy.wasir@yahoo.com

Persetujuan keikutsertaan dalam penelitian

(informed consent)

Saya yang bertandatangan dibawah ini:

Nama :.....

Alamat : .....

Nomor Hp : .....

E-mail : .....

Umur : .....

Pekerjaan : .....

Pendidikan Terakhir : .....

Peran partisipan :

9. Anggota Organisasi Kesehatan Dunia / *World Health Organization* (WHO)
10. Komite Penilaian Teknologi Kesehatan / Health Technology Assessment (HTA)
11. Komite Formularium Nasional
12. Instansi Penyelenggara Asuransi Kesehatan Nasional
13. Perusahaan Farmasi
14. Dokter
15. Apoteker
16. Pasien

Menyatakan bahwa, semua penjelasan tersebut telah disampaikan kepada saya sebagai partisipan dan semua pertanyaan saya telah dijawab oleh peneliti. Saya mengerti bahwa bila memerlukan penjelasan, saya dapat menanyakan kepada saudara Riswandy Wasir sebagai peneliti utama.

Dengan menandatangani formulir ini, saya setuju untuk ikut serta dalam penelitian ini

Tanggal:	Tanggal:
Tanda Tangan Partisipan	Tanda Tangan Peneliti
Nama Jelas: …….	Nama Jelas: Riswandy Wasir

S3 File. A formal waiver statements

University Medical Center Groningen

P.O. Box 30 001, 9700 RB Groningen, The Netherlands

Medical Ethics Review Board

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Fax +31 (0)50 361 43 51
E-mail metc@umcg.nl
Website: metcgroningen.nl

Ref. M18.236401

To
R. Wasir, MSc.
University Medical Center Groningen
Department of Epidemiology **FA 40**

Date: 30th August 2018
Subject: **The role of Health Technology Assessment for Pharmaceutical Pricing and Reimbursement Policy in Indonesia.**

Dear Sir,

I, the undersigned, declare that the submission entitled *"The role of Health Technology Assessment for Pharmaceutical Pricing and Reimbursement Policy in Indonesia"* by Wasir e.a., fulfils all the requirements for patient anonymity and is in agreement with regulations of our University Hospital for publication of patient data.

Sincerely,

W.A. Kamps MD PhD
chairman

cc -*T.L. Feenstra MD, University Medical Center Groningen, Department of Epidemiology FA 40*
-*E. Buskens, MD Ph.D, University Medical Center Groningen, Department Epidemiology FA40*

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